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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/722,843	11/25/2003	Robert J. Ternansky	34433/US/4/AMP/SKS	8174	
7590 11/01/2006		EXAMINER			
Jones Day 222 East 41st Street New York, NY 10017			CORDERO GARCIA, MARCELA M		
			ART UNIT	PAPER NUMBER	
			1654		
			DATE MAILED: 11/01/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)				
Office Action Summary		10/722,8	43	TERNANSKY ET AL.				
		Examine		Art Unit				
			1. Cordero Garcia	1654				
Period fo	The MAILING DATE of this communication or Reply	appears on th	cover sheet with the c	orrespondence ad	ddress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status					•			
1\⊠	Responsive to communication(s) filed on 11	1 August 2006	<b>:</b>					
2a)□	Responsive to communication(s) filed on <u>11 August 2006</u> .  This action is <b>FINAL</b> . 2b)⊠ This action is non-final.							
3)□	,—							
٥/١	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
	closed in accordance with the practice unde	ei Ex parte Qt	layle, 1935 C.D. 11, 40	03 O.G. 213.				
Disposit	ion of Claims							
4)🛛	4)⊠ Claim(s) <u>64-70</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.							
	S)⊠ Claim(s) <u>64-70</u> is/are rejected.							
7)	_							
• —	Claim(s) are subject to restriction and	d/or election r	equirement.					
	•		- 4					
	ion Papers		•					
	The specification is objected to by the Exam							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
	Applicant may not request that any objection to t	the drawing(s) b	e held in abeyance. See	e 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the corr	rection is requir	ed if the drawing(s) is obj	ected to. See 37 C	FR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ☐ All b) ☐ Some * c) ☐ None of:								
/-	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
	application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.								
oce the attached detailed Office action for a list of the certified copies not received.								
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Attachmen	t(s)							
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application								
) Motice of Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date <u>08/06 and 08/06</u> .  5) Notice of Informal Patent Application 6) Other:								
4)								

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 11, 2006 has been entered.

Applicants elected the species Ac-Pro-His-Ser-Cys(Ac)-Asn-Dox in the reply filed May 27, 2005. This species was searched and found free of the prior art. Therefore, Examiner elected a new species (Ac-Pro-His-Ser-Cys-Asn-NH<sub>2</sub>) from amongst those encompassed by the instant claims.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 64 is rejected under 35 U.S.C. 102(b) as being anticipated by Livant et al (Cancer Research, 2000, cited in the PTO-892 of 8/11/2005) or by Livant (US 6,001,965, citation A19 in the IDS of 08/11/06).

Both references teach a compound of Formula (V), Ac-Pro-His-Ser-Cys-Asn-NH<sub>2</sub> [Ac-PHSCN-NH<sub>2</sub>] wherein s is 0, r is 0, R<sub>30</sub> is Ac, X<sub>2</sub> is Pro, X<sub>3</sub> is His, X<sub>4</sub> is Ser, X<sub>5</sub> is Cys [y is 0, n is 1 and R<sub>13</sub> is H], X<sub>6</sub> is Asn [m is 1], R<sub>4</sub> is H and R<sub>31</sub> is H (e.g., abstract, lines 6-7 and 21-22 of Cancer Research and see, e.g., claims 1-3 of US 6,001,965).

Therefore, the references are deemed to anticipate the instant claim above.

### **Double Patenting**

Claims 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 19-20, 22-42, 55-56 and 58-59 of copending Application No. 10/723,144. The instantly claimed invention and the invention claimed in Application '144 are both drawn to a genus of compounds which contain overlapping subject matter. Further, the instantly claimed broad formula (V) of the instant application encompasses and/or is encompassed by the claimed broad formula (I) of Application '144.

This is a <u>provisional</u> obviousness-type double patenting rejection.

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#### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcela M Cordero Garcia, Ph. 19

Mande M Crolero Grade

Patent Examiner Art Unit 1654

MMCG 10/06

NISH GUPTA PRIMARY EXAMINER